

REMARKS

With entry of the present amendment, claims 24, 25, 27-34, 38-42, 51-55, 59-61, 67-68, 71-77 and 83-108 are pending. Claims 24, 25, 27-34, 38-42, 51-55, 59-61, 87 and 90 are allowed.

Claims 83 and 88 are amended to include reference to a buffer. No new matter is believed to be presented by the foregoing amendment.

Entry of this amendment and reconsideration of the claims, as amended and in view of the following remarks, is requested.

The Section 112 Rejection

Claims 83, 84, 88 and 89 are again rejected under 35 USC § 112, second paragraph, as being indefinite. Specifically the PTO alleges that the claimed compositions cannot have the asserted pH without including a buffer. This rejection is overcome.

Applicant reasserts his arguments already of record that the involved claims, all of which use the term comprising, properly claim the minimum number of components in the claimed pharmaceutical composition and a desired pH. Because applicant uses the term "comprising," applicant is not required to include in the claims all of the components that may yield such pH. Thus, it is applicant's position that the rejection is improper and the requirement for a buffer component is inappropriate. However, in an effort to expedite allowance of all of the pending claims, applicant has amended claims 83 and 88 to include a buffer. Support for this amendment is found throughout the specification, including for example at [0015] and [0039]. Claims 84 and 89 depend from claims 83 and 88, respectively, and thus now also include a buffer.

It is submitted that the Section 112 rejection of claims 83, 84, 88 and 89 is overcome and should be withdrawn.

The Section 102 Rejection

Claims 67-68, 71, 73, 75, 77, 83, 85, 86, 91-101 and 104 are again rejected under 35 USC § 102 (e) as being anticipated by US Patent No. 6,583,272 B1 (Bailon). Claim 106 is newly added to this rejection. This rejection is traversed.

In response to this rejection, applicant previously submitted a declaration of Dr. Appollon Papadimitriou under 37 CFR § 1.132. Dr. Papadimitriou is the sole inventor of the instant application. In his declaration, Dr. Papadimitriou averred that he is the sole inventor of formulations A-I presented in Example 8, Table 3, of the Bailon '272 reference patent. In the currently pending office action the PTO once again finds the Papadimitriou Declaration unsuitable, this time because the conditions of MPEP Sections 715.01 and 716.10 are allegedly not met. Specifically, it is the PTO's position that the Papadimitriou Declaration is not proper because "in the instance [sic] case, Dr. Papadimitriou is not a joint inventor of the 6,583,272 patent, and Pascal Sebastian Bailon is not a joint inventor of the instant application, thus the condition for filing an affidavit or a declaration under 37 CFR 1.131 showing prior invention or an unequivocal declaration under 37 CFR 1.132 to overcome 102(e) rejection has not been met. Therefore, the declaration of Dr. Papadimitriou filed under 37 CFR 1.132 is not accepted to overcome the rejection under 102(e)." Applicant submits the PTO's interpretation of MPEP Sections 715.01 and 716, and the conditions pursuant to which a Rule 132 Declaration may be used to overcome a Section 102(e) rejection, are legally incorrect and should be withdrawn.

First, applicant submits the PTO considered the wrong portion of MPEP § 715.01. Applicant agrees with the Examiner that the fact pattern presented in the instant case is not one of joint inventorship (Section 715.01(a)) or common assignee (Section 715.01(b)). However, there are other parts to Section 715.01 and these clearly support applicant. Specifically applicant directs the Examiner's attention to the introductory paragraphs of Section 715.01, in particular the paragraph immediately preceding Section 715.01(a). Also, reference is made to Section 715.01(c), the paragraph entitled

"Derivation." It is submitted that these sections, and the cases cited therein, clearly support the propriety of the Papadimitriou Declaration.

Furthermore, the case law supports applicant's position. For example, the Examiner's attention is directed to In re Mathews, 161 USPQ 176 (CCPA 1969)(copy enclosed), which is cited in the Derivation paragraph of Section 715.01(c). The fact pattern in Mathews is very similar, though not exact, to that presented in the instant case. In Mathews a patent to sole inventor Dewey contained a disclosure describing in full the invention that was subsequently claimed by inventor Mathews in the application on appeal. Mathews was a co-worker of Dewey. The Mathews application was filed 18 months after the Dewey application was filed, but before the Dewey application matured into a patent. Both cases involved sole inventors. Applicant submits herewith a copy of Dewey patent 3,105,920 showing that Dewey was listed as a sole inventor. The Patent Office rejected the subsequently filed Mathews application under Section 102(e) in view of the earlier disclosure of the Mathews work in the Dewey patent. Mathews submitted a declaration of Dewey under Rule 132 stating that the unclaimed subject matter disclosed in his patent was not his invention but was rather disclosed to him by Mathews. The PTO did not accept the Dewey Declaration insisting that a Rule 131 Declaration by Mathews was needed instead. The CCPA reversed holding "that a Rule 131 affidavit is not the only way of antedating a reference" and that a Rule 132 affidavit could also be used. *Id* at 279. All that is required is that a proper showing of facts be made evidencing that the prior unclaimed disclosure was that of applicant's own invention. See, In re Facius, 161 USPQ 294, 300-301 (copy enclosed).

Nothing in 37 CFR 1.132 requires that a declaration submitted pursuant to this rule can only be made when there are joint inventors or that the declaration must be made by the inventor of the reference patent or the subsequent applicant. The Declaration of either would be acceptable. All that is needed is a proper showing of facts and that is how the courts have interpreted this Rule. In the instant case, the PTO has cited no precedent

or evidence that the Papadimitriou Declaration is not a proper or persuasive showing. Applicant submits therefore that the Declaration must be accepted for what it avers.

Moreover, with respect to MPEP Section 716.10, the Board of Appeals and the CCPA also agree with applicant's position that joint inventorship of applications is not required for use of a Rule 1.132 Declaration to establish prior invention. For example, the Examiner's attention is directed to In re Cloke, 2002 WL 1821684 (Bd. Pat. App. & Interf., 2002) (Appeal No. 200-0379)(Slip Opinion copy enclosed), which while not citable as binding precedent, certainly evidences how the Board interprets MPEP Section 716.10 in relation to Rule 1.132 Declarations. The fact pattern in In re Cloke was analogous to that herein presented. The Examiner held a Rule 132 declaration (the Hull declaration) insufficient to overcome a Section 102(e) rejection because

All of the case law cited by Appellant and in the MPEP section 716.10 pertains to overlapping inventors or assignees....In the instant case, there are no common inventors or assignee. Hence, the fact pattern of [A]ppellant's case does not follow the fact pattern of the case law cited by the MPEP section 716.10.

Reversing, the Board disagreed with the PTO stating that joint inventorship is not a requirement for demonstrating "that the applicant is the inventor of the subject matter relied on in the reference patent." In re Cloke, Slip Opinion at page 8. The case law cited by the Board fully supports its decision that the courts did not require the patentee of the reference patent to submit a Section 1.132 declaration disclaiming the subject matter at issue. Thus, as a disclaimer of non-invention is not a requirement to overcome a 102(e) rejection, neither is joint invention a requirement. See, e.g. In re DeBaun, 214 SUP 933, 934 n.4 (CCPA 1982) (holding that a disclaiming affidavit by coinventor of reference patent is not required).

The Examiner's attention is directed in particular to footnote 3, page 10, of Cloke, wherein in clarifying the MPEP § 716.10 citation to In re Kroger, 219 USPQ 370 (Bd. Pat. App. 1982), the Board notes:

Because the reference in Kroger was an article rather than a patent, the Board's construction of Facius, Mathews, and Carriera [sic] as requiring a patentee to 'disclaim the subject matter and attribute it to the applicant,' constitutes non-binding dictum, which we note is not mentioned in MPEP §716.10.

Citation omitted.

Thus, contrary to the PTO's interpretation of MPEP § 716.10 in the pending rejection in the instant case, the Board in Cloke makes clear that this section of the MPEP supports applicant's position that the Rule 132 Declaration of Dr. Papadimitriou submitted in the instant case is proper and overcomes the pending 102(e) rejection:

MPEP § 716.10 is consistent with this conclusion. That section gives as Example 2 a reference in which 'the author or patentee is an entity different from applicant' and explains that '[i]n the situation described in Example 2, an affidavit under 37 CFR 1.132 may be submitted to show that the relevant portions of the reference originated with or were obtained from the applicant.'

Id. Slip Opinion at page 11 n.4.

In conclusion, the PTO's assertion that the Papadimitriou Rule 132 Declaration is insufficient to overcome the pending 102(e) rejection because there is no common inventor between the Bailon '272 patent and the instant application is legally incorrect, and the rejection should be withdrawn.

Claim Objections

Claims 72, 74, 76, 102, 103, 105, 107 and 108 are objected to because these claims depend from a rejected base claim but are otherwise allowable. For the reasons stated above, the rejection under Section 102(e) of base claims 71, 73, 75, 101 and 104 from with the foregoing claims depend is legally unsound, and as such, all of these claims are allowable in their current condition.

CONCLUSION

Applicant submits this Amendment is fully responsive to all of the issues raised in the Office Action issued December 23, 2005, and that all pending claims are allowable. Early and favorable consideration is earnestly solicited.

If the Examiner believes there are other issues that can be resolved by telephone interview, or that there are any informalities remaining in the application which may be corrected by Examiner's Amendment, a telephone call to the undersigned attorney is respectfully solicited.

Applicants believe that no fee is due with this communication. However, should the Patent Office determine that a fee is owed, or a credit is due to applicant, the Patent Office is hereby authorized to charge any required fees, including any extension of time and/or excess claim fees, or credit any overpayment, to applicant's Deposit Account 08-2525 as appropriate.

Respectfully submitted,



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Attachments

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